



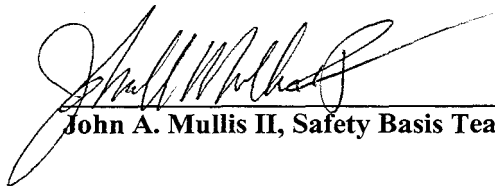
**Department of Energy
Oak Ridge Operations
Office of Environmental Management
Procedure**



Safety Basis Document Review

**EM-3.5
Revision 0**

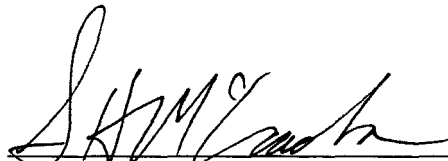
Prepared:



John A. Mullis II, Safety Basis Team Leader

10/19/2004
Date

Approved:



**Stephen H. McCracken,
Assistant Manager for Environmental Management**

10/25/04
Date



Department of Energy
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Concurrence		
Rtg. Symbol	EM-90	
Initials	Mullis	
Date	10/19/04	
Rtg. Symbol	EM-94	
Initials	Oldham	
Date	10/19/04	
Rtg. Symbol	EM-90	
Initials	Boege	
Date	10/29/04	
Rtg. Symbol	EM-90	
Initials	McCracken	
Date	10/25/04	
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Revision Log

Revision	Description of the Revision	Issue Date
0	Initial Issue.	10/25/04

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List of Acronyms

AC	Administrative Control
AMEM	Assistant Manager for Environmental Management
BJC	Bechtel Jacobs Company LLC
CFR	Code of Federal Regulations
COA	Condition of Approval
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
EM	Environmental Management
HAD	Hazards Assessment Document
JCO	Justification for Continued Operation
ORO	Oak Ridge Operations Office
SBT	Safety Basis Team
SER	Safety Evaluation Report
SME	Subject Matter Expert
TSR	Technical Safety Requirement
USQ	Unreviewed Safety Question

1.0 PURPOSE

This procedure correlates to the ORO O 420, Chapter XIII, Change 2, SAFETY BASIS DOCUMENTS REVIEW SYSTEM, dated July 19, 2004, by documenting the process for assigning responsibility, accountability and providing administrative guidance to Environmental Management (EM) Oak Ridge Operations Office (ORO) for the review and approval of safety basis documents.

2.0 SCOPE

This procedure is applicable to review of safety basis documents for facilities under the management of Oak Ridge Operations Office of Environmental Management that are submitted by prime contractors for new and existing Hazard Category 1, 2, or 3 nuclear facilities, including major modifications. This includes facilities that have been downgraded to below Hazard Category 3 by analysis. Included are review requirements for Documented Safety Analysis (DSA), Technical Safety Requirements (TSRs), Hazard Assessment Documents (HADs), Potential Inadequate Safety Analysis (PISA), Justification for Continued Operation (JCOs), Inactive Waste Sites (IWSs) and writing Safety Evaluation Reports. Nothing in this procedure changes any requirements contained in any Department of Energy (DOE) directive, standard, or regulation.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 10 CFR Part 830, *Nuclear Safety Management*, January 2001.
- 3.1.2 ORO O 420, Chapter XIII, *Safety Basis Documents Review System*, Change 2, July 19, 2002.
- 3.1.3 ORO G 420.13, *Safety Basis Document Review Guide*, July 19, 2004
- 3.1.4 ORO O 420, Chapter XIV, *Delegation of Approval Authority for Safety Basis Documents*, July 24, 2002.
- 3.1.5 DOE O 231.1A, *Environment, Safety, and Health Reporting*, August 2003.
- 3.1.6 ORO M 100, Chapter I, Change 3, *ORO MANAGEMENT SYSTEM DESCRIPTION*, June 1, 2004
- 3.1.7 Memorandum from Jesse Hill Roberson, *Supplemental Environmental Management (EM) Guidance for Implementing 10 CFR 830, Subpart B, Safety Basis Requirements*, May 28, 2002

3.2 Definitions

- 3.2.1 Documented Safety Analysis. A documented analysis of the extent to which a nuclear facility can be operated safely with respect to the workers, the public and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.
- 3.2.2 Technical Safety Requirements. The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include (as appropriate for the work and the hazards identified in the DSA for the facility) the safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions and design features, as well as a bases appendix.
- 3.2.3 Hazards Assessment Document. A safety basis document which documents the Final Hazard Category of a facility. A HAD contains analysis that shows that a facility is less than Hazard Category 3 based on analysis. Since a HAD performs Final Hazard Categorization, it must be approved by DOE through the issuance of an SER.
- 3.2.4 Justification for Continued Operation. A document requesting DOE's approval of operation on a temporary basis after identifying a PISA, USQ, or other condition where the current safety basis requirements cannot be fully met or do not address the identified concern.
- 3.2.5 Verification Report. The report that DOE prepares to establish that Inactive Waste Site documentation demonstrates that the subject EM managed site(s) meets the EM-1 Inactive Waste Site Criteria.
- 3.2.6 Potential Inadequacy in the Safety Analysis. A PISA is an issue or problem for which the extent of impact on the safety analysis is not known. However, there exists sufficient possibility that after further evaluation, the safety analysis supporting the safety basis will be found inadequate or the margin of safety will be found to be reduced.
- 3.2.7 Unresolved Safety Question. A situation where (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the DSA could be increased, (2) the possibility of an accident or malfunction of a different type than any previously evaluated in the DSA could be created, (3) a margin of safety could be reduced, or (4) the DSA may not be bounding or may be otherwise inadequate.
- 3.2.8 Safety Evaluation Report. The report that DOE prepares to document (1) the sufficiency of the safety basis document(s) for a Hazard Category 1, 2, or 3

nuclear facility, (2) the extent to which a contractor has satisfied the requirements of 10 CFR 830, Subpart B, and (3) the basis for DOE's approval of the facility's safety basis document(s), including any conditions of approval.

- 3.2.9 Government Furnished Services and Items. The contractual agreement between DOE and Bechtel Jacobs Company LLC that within thirty (30) calendar days after the effective date of the contract and by September 1 prior to each fiscal year end, the contractor shall provide the CO a projection of its needed Government Furnished Services and Items (GFS&I), identified in the H-4 Clause table (page H-12 of contract DE-AC05-98OR22700).

4.0 RESPONSIBILITIES

4.1 Assistant Manager for Environmental Management

- 4.1.1 Ensures that the contractors develop safety basis documents in accordance with 10 CFR 830, Subpart B and established DOE requirements.
- 4.1.2 Establishes a management process consistent with regulatory and Departmental expectations for the review and approval of safety basis documents.
- 4.1.3 Approves safety basis reviewer qualifications.
- 4.1.4 Ensures that guidance is provided to contractors concerning safety basis issues, when necessary.
- 4.1.5 Ensures that the Safety Basis Team reviews submitted safety basis documents for technical accuracy and compliance with 10 CFR 830 and established DOE requirements within established timeframes and documents the results of the reviews.
- 4.1.6 Ensures that the Safety Basis Team Leader resolves issues, comments, and differing technical opinions that cannot be satisfactorily resolved by the reviewers.
- 4.1.7 Approves SERs and their corresponding safety basis documents where the approval authority has been delegated.
- 4.1.8 Resolves differing technical opinions when Safety Basis Team Leader cannot.
- 4.1.9 Concurs on VR/SER(s) prior to sending VR/SER to the Approval Authority for Approval when Approval Authority is not delegated.

4.2 Safety Basis Team Leader

- 4.2.1 Assigns the reviews of contractor USQ procedures, DSA, TSR, HAD, PISA, JCO and IWSs to Lead Reviewers that meet the qualification requirements specified in Reference 3.1.2.
- 4.2.2 Resolves comments/issues that cannot be satisfactorily resolved by the Lead Reviewer.
- 4.2.3 Reviews SER/VR(s) for technical adequacy
- 4.2.4 Recommends approval of SER/VR(s) and related correspondence to the to the AMEM or his designate.
- 4.2.5 Develops guidance concerning Safety Basis issues.
- 4.2.6 Documents Safety Basis reviewer qualifications and submits qualifications to AMEM for approval.
- 4.2.7 Ensures that an assessment of the contractors' USQD Process is performed at least annually.

4.3 Lead Reviewer

- 4.3.1 Obtains a copy of contractor submitted USQ procedure(s), DSA, TSR, HAD, PISA, or JCO as assigned by the line Safety Basis Team Leader.
- 4.3.2 Enlists the help of a review team, as necessary.
- 4.3.4 Reviews the contractor submittal against elements identified in the review process (section 5.0).
- 4.3.5 Notifies the prime contractor that the document cannot be approved through the Contracting Officer's Representative (COR) with the basis for disapproval clearly documented if document is determined to be unapprovable.
- 4.3.6 Prepares SER/VR(s) to document DOE's basis for approval of contractor submitted USQ procedure(s), DSAs, TSRs, HADs, Change Packages, JCOs, or IWSs.

4.4 Safety Basis Team Project Coordinator

- 4.4.1 Receives, logs, files and distributes all incoming documents and all associated

correspondence.

- 4.4.2 Maintains document status, priorities, Lead Reviewers assignments and DOE approval duration due dates in the SBT Project Status log.
- 4.4.3 Ensures that the Safety Basis Document List is maintained and that the information contained therein is up to date.
- 4.4.4 Coordinates all SBT meetings, prepares correspondence in association with the SBT documents and tracks all incoming and outgoing document and correspondence transmittals.
- 4.4.5 Communicates priorities to EM Headquarters Approval Authority staff and assists with all issues related to documents and correspondence transmitted by the SBT.
- 4.4.6 Prepares metrics for the SBT Leader's monthly performance review and maintains Headquarters level spreadsheet with current Oak Ridge Safety Basis Document information to include ensuring hard copies of all revisions are available at Headquarters.

5.0 REQUIREMENTS AND PROCEDURES

5.1 General Requirements for the Safety Basis Review and Approval Process

NOTE: this section contains requirements applicable to all safety basis documents submitted to EM for review. Requirements unique to the review and approval process for each type of safety basis document is provided in later sections.

- 5.1.1 The SBT Leader identifies a Lead Reviewer (SER/VR preparer) and a technical reviewer if required.

Note: The Lead Reviewer and technical reviewer shall be selected from the list of approved reviewers (Reference paragraphs 4.1.3 and 4.2.6). Alternate qualifications bases on knowledge and experience of "under the supervision of a qualified individual" may be considered if they are approved by the responsible Assistant Manager. The identification of a technical reviewer is not required for team review, since multiple reviewers are already engaged in the process.

- 5.1.2 The Safety Basis Team Leader assigns a unique number to each SER/VR and logs that the number into the Safety Basis Team Project Log.
Note: For GFS&I a due date is establishes bases on the document type as found in Bechtel Jacobs Company LLC's contract-clause H-4. For non-GFS&I, the Safety Basis Team Leader established the need date in

consultation with the DOE Project Director assigned to the facility. However, the 90 day review duration established in Reference 3.1.7 by EM-1 cannot be exceeded without Approval Authority and AMEM concurrence.

- 5.1.3 The Safety Basis Team Leader reviews all SER/VR(s) to verify that the SER/VR is comprehensive and technically adequate.
- 5.1.4 When the SER/VR is ready for approval an approval package shall be prepared which includes the SER/VR and a transmittal memorandum.
- 5.1.5 The Lead Reviewer signs the SER/VR and forwards the package to the Safety Basis Team Leader. The Safety Basis Team leader signs the SER/VR and forwards it to the AMEM who then concurs with the SER or VR and forwards the package to the Approval Authority for approval via the ORO Manager.
- 5.1.6 When the SER or VR is approved, the COR formally transmits the SER or VR to the contractor. The transmittal letter establishes any expectations regarding implementation issues.
- 5.1.7 The Safety Basis Team Project Coordinator ensures that the safety basis list EM Technical Support and Assessment Division ensures that the safety basis list has been updated, as updating the safety basis list is our responsibility.

5.2 Documented Safety Analysis (DSA), Technical Safety Requirements (TSR), Justifications for Continued Operations, and associated Change Packages

5.2.1 The Lead Reviewer performs the following:

- 5.2.1.1 Evaluates the scope of the review effort to determine if additional resources are required and if a review plan is warranted. Use of a review plan and a multi-disciplined review team are required for the initial issuance of safety basis documents or for substantial changes to existing documents, commensurate with the level of complexity and hazards of the facility (graded approach).

- NOTE. (1) Substantial changes include: additions of new hazards, new methods or analytical approach, or new controls that significantly affect a safety basis document.
- (2) Review team members shall include facility representatives and program managers even if a multi-disciplined review team is not required
 - (3) Reference 3.1.3, Safety Basis Document Review Guide

- contains guidance on preparing a review plan.
- 5.2.1.2 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. Guidelines for determining the technical adequacy of the Hazards Analysis and Control Selection are contained in Reference 3.1.3, Safety Basis Document Review Guide. The DOE Project Manager and Facility Representative should assist in the review of the document.
- 5.2.1.3 Promptly communicates comments/issues generated during the review to the prime contractor. The Lead Reviewer elevates areas where agreement cannot be reached through the chain of command for resolution. The DOE Project Manager and Facility Representative should be kept informed of issues generated during the review.
- 5.2.1.4 If EM is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the Lead Reviewer formally notifies the prime contractor that the document cannot be approved through the COR with the basis for disapproval clearly documented.
NOTE. This step is a "should" because it may be skipped if the prime contractor voluntarily submits a modified document based on DOE's comments prior to receiving an official rejection letter.
- 5.2.1.5 Prepares an SER (or coordinates the review team's input on the SER) for safety basis documents for new or existing Hazard Category 2, or 3 nuclear facilities and/or major modifications and for revisions/updates to compliant safety basis documents.
NOTE. (1) A supplement to an existing SER may be sufficient for an annual update, TSR Change, JCO or minor DSA changes.
(2) JCO expectations regarding content and applicability are contained in the Lead Reviewer's Manual.
- 5.2.1.6 The SER must be prepared and issued in accordance with DOE-STD-1104-96, REVIEW AND APPROVAL OF NONREACTOR NUCLEAR FACILITY SAFETY ANALYSIS REPORTS to document the basis for EM's approval of the safety basis document. This should be accomplished by following the instructions for SER preparation provided in Reference 3.1.3, Safety Basis Document Review Guide.
- 5.2.1.7 The Lead Reviewer must ensure that any DOE Conditions for Approval (COA) in the SER constitute an appropriate and minimal essential set of conditions that are clearly stated to facilitate its implementation.

5.3 Inactive Waste Sites (IWS)

5.3.1 For facilities that meet the EM-1 criteria as an Inactive Waste Site, the Lead Reviewer:

5.3.1.1 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. The EM-1 Inactive Waste Site Criteria can be found in Reference 3.1.3, Safety Basis Document Review Guide.

5.3.1.2 Promptly communicates comments/issues generated during the review to the prime contractor through the COR. The Lead Reviewer elevates areas where agreement cannot be reached through the chain of command for resolution. The DOE Project Manager should participate in the review and be kept informed of issues and associated resolutions.

5.3.1.3 If DOE is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the Lead Reviewer formally notifies the prime contractor that the document cannot be approved through the COR with the basis for DOE's disapproval clearly documented.

NOTE: This step is a "should" because it may be skipped if the prime contractor voluntarily submits a modified document based on DOE's comments prior to receiving an official rejection letter.

5.3.1.4 Prepares a VR in accordance with the instructions found in the Ref. 3.1.3, Safety Basis Document Review Guide.

5.3.1.5 The Lead Reviewer must ensure that any DOE conditions for approval in the VR constitute an appropriate and minimal essential set of conditions that are clearly stated to facilitate its implementation.

5.4 Final Hazard Categorization Documents

5.4.1 The Lead Reviewer performs a review of the assigned final hazard categorization document to ensure its technical adequacy and conformance with the Final Hazard Categorization Document Guidance provided in the Ref. 3.1.3, Safety Basis Document Review Guide. The DOE Project Manager and Facility Representative should participate in the review and be kept informed of issues and associated resolutions.

5.4.2 The Lead Reviewer interfaces with the prime contractor to address any issues identified during the review. If DOE is unable to approve substantial clarification and/or numerous conditions for approval, the Lead Reviewer formally notifies the prime contractor that the document cannot be approved through the COR with the basis for

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DOE's disapproval clearly documented.

- 5.4.3 The Lead Reviewer prepares an SER for the Final Hazard Categorization Document to document the DOE basis for approval of Hazard Category 2 or 3 nuclear facilities that have been recategorized as less than Hazard Category 3 (e.g., Radiological) by analysis.
- 5.4.4 The Lead Reviewer must ensure that any DOE conditions for approval in the SER constitute an appropriate and minimal essential set of conditions that are clearly stated to facilitate its implementation.

5.5 Records

The following records must be controlled and maintained by the Safety Basis Team Leader:

- 5.5.1 SERs and supporting documentation associated with DOE's review and approval of a safety basis document (e.g., review comments, matrices, transmittal correspondence between the prime contractor and DOE, independent analyses or calculations performed by or for DOE).
- 5.5.2 Annual summary report(s) of all prime contractors USQ determinations and any correspondence associated with the DOE determination of the adequacy of the summary report.
- 5.5.3 USQ correspondence between the prime contractor and DOE and any related documentation (e.g., notifications, schedule for resolution, compensatory actions, JCOs).

6.0 ATTACHMENTS

6.1 Attachment A

Comment Resolution Form

Attachment A

Comment Resolution Form

ATTACHMENT A

USQ Procedure Comment Resolution Form

Procedure No. and Revision: _____

Reviewer: _____

Comment No.	Comment(s)	Rule Ref.	Resolution